IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA	§	**PLAINTIFF**
v.	§	**Civil No. 1:24-cv-160-HSO-BWR**
LYNN FITCH *in her official capacity as Attorney General of the State of Mississippi*	§	**DEFENDANT**

MEMORANDUM OPINION AND ORDER DENYING MOTION [7] FOR PRELIMINARY INJUNCTION

This matter comes before the Court on Plaintiff Pharmaceutical Research and Manufacturers of America's ("PhRMA" or "Plaintiff") Motion [7] for Preliminary Injunction. Having considered the allegations set forth in Plaintiff's Complaint [1], the parties' Memoranda [8], [15], and relevant legal authority, and having heard argument at a hearing held on June 27, 2024, the Court will deny the Motion [7].

I. INTRODUCTION

Plaintiff's Motion [7] asks the Court to enjoin the enforcement of Mississippi's recently enacted "Defending Affordable Prescription Drug Costs Act," 2024 Miss. H.B. 728 ("H.B. 728"), which is set to take effect on July 1, 2024. House Bill 728 concerns a federal program referred to as Section 340B. *See* 42 U.S.C. § 256b. Under Section 340B, pharmaceutical manufacturers who participate in Medicaid and Medicare Part B must offer certain drugs at discounted prices to certain healthcare providers, called "covered entities," that generally provide care for the

poor. *See infra*, Part I.A. In essence, H.B. 728 requires manufacturers to deliver drugs ordered through the 340B program to for-profit pharmacies called "contract pharmacies" with which covered entities have arrangements under which the pharmacy will dispense discounted drugs to the covered entity's patients.

Plaintiff claims that H.B. 728, in requiring its members to deliver discounted drugs to an unlimited number of contract pharmacies, invalidly expands their obligation to provide discounted drugs to covered entities. *See* Memo [8] at 14–29. It asserts that H.B. 728 is preempted by § 256b. *See id.* Plaintiff also claims that H.B. 728 unconstitutionally regulates out-of-state conduct, and that it is unconstitutionally vague. *See id.* at 30–33. Plaintiff therefore seeks a preliminary injunction to stay the enforcement of H.B. 728. Because it is unable to satisfy the necessary elements for such relief, Plaintiff's Motion [7] will be denied.

A. The Section 340B program

Section 340B requires pharmaceutical manufacturers that want the federal government to cover their drugs under Medicaid and Medicare Part B to provide discounts on their drugs to certain healthcare providers. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5); *see Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Those healthcare providers are "called '340B' or 'covered' entities," and "include public hospitals and community health centers, many of" which are "providers of safety-net services to the poor." *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). The 340B Program "is

superintended by the Health Resources and Services Administration," ("HRSA"), "a unit of the Department of Health and Human Services," ("HHS"). *Id.*

"Drug manufacturers," including Plaintiff's members, "opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement" ("PPA") "used nationwide." *Id.* These agreements "are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Id.* PPAs must "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." § 256b(a)(1).

Through Section 340B, Congress leverages the federal government's market power in healthcare—Medicare and Medicaid cover "almost half the annual nationwide spending on prescription drugs," *Sanofi Aventis*, 58 F.4th at 699 (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022))—to aid covered entities in their mission to care for low-income Americans, *see id.* The statute enables covered entities "to give uninsured patients drugs at little or no cost." *Id.* Covered entities also obtain "extra revenue from serving insured patients" because "they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Id.* (citing Gov't Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (GAO-11-836, Sept. 2011)).

Section 340B contains two provisions that prohibit covered entities from abusing their ability to obtain discounted drugs. Covered entities cannot "resell or otherwise transfer" discounted drugs "to a person who is not a patient of the entity." § 256b(a)(5)(B). Covered entities also cannot obtain "duplicate discounts or rebates," meaning they cannot obtain Medicaid rebates under title XIX of the Social Security Act, *see* 42 U.S.C. § 1396 *et seq.*, for drugs that they purchase at a discount under Section 340B, *see* § 256b(a)(5)(A)(i).

To ensure covered entities do not resell discounted drugs or obtain duplicate discounts, the statute contains an auditing provision. It states:

> A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

§ 256b(a)(5)(C). And "[i]f the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing," that the covered entity illegally resold discounted drugs or obtained duplicate discounts, "the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug . . . provided under the agreement between the entity and the manufacturer." § 256b(a)(5)(D).

The Secretary can impose additional sanctions. Covered entities that the Secretary finds knowingly and intentionally resold discounted drugs must "pay a monetary penalty to a manufacturer or manufacturers in the form of interest on

sums for which the covered entity is found liable under [§ 256(a)(5)(D)]." § 256b(d)(2)(B)(v)(I). Where the Secretary finds the covered entity's reselling "was systematic and egregious as well as knowing and intentional," the Secretary can remove the covered entity from the program entirely. § 256b(d)(2)(B)(v)(II).

B. The dispensation of 340B drugs at contract pharmacies and related litigation

The issue in this case concerns a matter notably absent from the foregoing discussion: how discounted drugs under Section 340B are to be delivered to patients of covered entities. Between 1996 and March 2010, HRSA's 1996 Guidance "acknowledged that section 340B 'is silent as to permissible drug distribution systems,' but it nonetheless sought to fill 'gaps in the legislation' and thereby 'move the program forward.'" *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C. Cir. 2024) (quoting Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) ("1996 Guidance")). Given that "many covered entities use outside pharmacies to distribute drugs to their patients," HRSA's 1996 Guidance "stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location." *Id.* at 457 (citing 1996 Guidance at 43,555). The 1996 Guidance also required that, "in directing shipments to its contract pharmacy," the covered entity "must retain title to the drugs and thus 'be responsible' for any diversion or duplicate discounts." *Id.* (citing 1996 Guidance at 43,553).

In 2010, HRSA shifted course. HRSA's 2010 Guidance took the position that "covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies." *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) ("2010 Guidance")). In its view, this Guidance "would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients." 2010 Guidance at 10,273. HRSA did not change its view that covered entities "must maintain title to and responsibility for the drugs." *Novartis*, 102 F.4th at 457 (citing 2010 Guidance at 10,277). HRSA considered comments following the release of proposed guidelines in 2007, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1,540 (Jan. 12, 2007), asserting that allowing covered entities to dispense Section 340B drugs through multiple contract pharmacies would enable diversion and duplicate discounts, *see* 2010 Guidance at 10,272–75. But it ultimately decided that covered entities could use multiple contract pharmacies if "they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition," including that "[a]uditable records must be maintained to demonstrate compliance with those requirements." *Id.* at 10,273.

In 2020, many pharmaceutical manufacturers sought to prevent covered entities from using multiple contract pharmacies to dispense Section 340B drugs by

implementing policies "limit[ing] the number and kinds of contract pharmacies to which they would ship orders." *Novartis*, 102 F.4th at 458. As Plaintiff argues in its Memorandum [8], pharmaceutical manufacturers were and remain concerned about the model covered entities and contract pharmacies often use in dispensing and accounting for Section 340B drugs. *See* Memo [8] at 8–10. Plaintiff refers to that model as the "replenishment model." *Id.* Put simply, under this model, a contract pharmacy first dispenses prescription drugs to all its customers from one supply of drugs, which it purchased at full price from the manufacturer. *Id.* After dispensing the drugs, the pharmacy—or a third-party administrator—determines which customers were covered-entity patients. *Id.* The pharmacy then informs the covered entity of the quantity of drugs it dispensed to the entity's patients. *Id.* The covered entity then places an order of Section 340B drugs in that quantity as a "replenishment" of the drugs dispensed to covered-entity patients.[1] *See id.*

As the D.C. Circuit recognized, "[m]anufacturers," such as Plaintiff's members, "have argued that these arrangements lead to unlawful diversion and duplicate discounts." *Novartis*, 102 F.4th at 458. Under the replenishment model, "[t]he covered entity [and] the pharmacy . . . often divvy up the spread between the discounted price and the higher insurance reimbursement rate." *Id.* at 457. So, covered entities and contract pharmacies both have "a financial incentive

[1] *Novartis* stated that "the pharmacy places an order to replenish its section 340B purchases," as opposed to the covered entity. 102 F.4th 457. An Office of Inspector General report that it cited states that, given the quantity of drugs dispensed to covered-entity patients at the pharmacy, "the covered entity purchases that quantity of the drug at the discounted 340B price and has it delivered to the contract pharmacy." S. Wright, Off. of the Inspector Gen., OEI-05-13-00431, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 5 (2014).

to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457–58.

In 2020, HHS, concerned about manufacturers' policies limiting covered-entity patients' access to medications, issued an advisory opinion stating that pharmaceutical manufacturers are *required* to ship Section 340B drugs to an unlimited number of contract pharmacies. *See Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020), https://perma.cc/L7W2-H597 ("2020 Advisory Opinion")). "HHS reasoned that 340B drugs are 'purchased by' a covered entity no matter how they are distributed," and so, "the 'situs of delivery . . . is irrelevant.'" *Id.* at 701 (citing 2020 Advisory Opinion at 1–3). Both the Third Circuit and the D.C. Circuit concluded, however, that Section 340B is silent about delivery, and that the federal statute's requirement that manufacturers offer discounts to covered entities did not implicitly permit HHS to mandate that they comply with any delivery practice the covered entities desire. *See id.* at 703–06; *Novartis*, 102 F.4th at 460–63.

In response, states have begun to impose explicitly what HHS had purported to impose by guidance. For example, in 2021, Arkansas enacted Act 1103, which "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying the pharmacy access to a covered entity's 340B drugs," and "prohibits pharmaceutical manufacturers from interfering in a covered entity's agreement with a contract pharmacy by denying 340B drug

pricing to covered entities who use contract pharmacies for distribution." *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604(c)). The Pharmaceutical Research and Manufacturers of America, an association of pharmaceutical manufacturers—Plaintiff here as well—sought an injunction against enforcement of the Arkansas law on a theory that Section 340B preempts it. *Id.* at 1139–40. The Eighth Circuit, however, disagreed. *Id.* As to field preemption, the Eighth Circuit concluded that "the 340B Program is not so pervasive that Congress left no room for the States to supplement it," given that the statute is "'is silent about delivery' of drugs to patients." *Id.* at 1143 (quoting *Sanofi Aventis U.S. LLC*, 58 F.4th at 703) (other quotation marks and citation omitted). Concerning conflict preemption, because the Arkansas law "does not require manufacturers to provide 340B pricing discounts to contract pharmacies," and "does not set or enforce discount pricing," the Eighth Circuit found that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to the statute's purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law "assists in fulfilling the purpose of 340B," in that it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

On April 12, 2024, the Governor of Mississippi signed H.B. 728, which had been enacted by the state legislature. Ex. [14-1] (H.B. 728). House Bill 728 provides that "[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug

by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity." H.B. 728 § 4. The law defines a "340B drug" as a covered outpatient drug "that has been subject to any offer for reduced prices by a manufacturer pursuant to [Section 340B]." H.B. 728 § 2(a). A violation of H.B. 728 constitutes a violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 *et seq*, *see* H.B. 728 § 5, which provides for both civil and criminal penalties and is enforced by Mississippi's Attorney General, *see* Miss Code Ann. §§ 75-24-9 (covering injunctive relief), 75-24-19 (covering civil penalties for violations of injunctions issued under § 75-24-9, and for knowing and willful violations of the statute), 75-24-20 (covering criminal penalties for knowing and willful violations). House Bill 728 does not, however, create any private right of action. H.B. 728 § 5.

C. Procedural history

On May 30, 2024, Plaintiff filed a Complaint [1] in this Court seeking a declaratory judgment under 28 U.S.C. § 2201 that H.B. 728 is preempted by federal law; that H.B. 728 violates the dormant Commerce Clause and the Due Process Clause by regulating out-of-state commerce; and that H.B. 728 is unconstitutionally vague. *See* Compl. [1] at 47. It likewise sought temporary, preliminary, and permanent injunctive relief against the Attorney General of Mississippi, enjoining her from enforcing H.B. 728 against Plaintiff's members. *Id.* at 47. Plaintiff filed a Motion [7] for Preliminary Injunction on June 17, 2024, and argues that H.B. 728 is

unconstitutional under the theories alleged in the Complaint [1]. *See generally* Memo [8]. Defendant, Attorney General Lynn Fitch ("Defendant"), responded on June 24, 2024, Resp. [14], and The American Hospital Association, 340B Health, the Mississippi Hospital Association, and the Rural Hospital Alliance filed an Amicus Brief [17] on June 25, 2024, in support of Defendant. The Court held a hearing on the Motion [7] on June 27, 2024.

II. DISCUSSION

A party seeking a preliminary injunction must show: "(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest." *Clark v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 640–41 (5th Cir. 2023); *see* Fed. R. Civ. P. 65. Factors three and four, "[t]he balance-of-harms and public-interest factors[,] merge when the government opposes an injunction." *Career Colleges & Sch. of Texas v. United States Dep't of Educ.*, 98 F.4th 220, 254 (5th Cir. 2024) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). "A preliminary injunction is an extraordinary remedy and should be granted only if the movant has clearly carried the burden of persuasion with respect to all four factors." *Allied Mktg. Grp., Inc. v. CDL Mktg., Inc.*, 878 F.2d 806, 809 (5th Cir. 1989).

Plaintiff cannot satisfy the first requirement because it has not demonstrated a "substantial likelihood of success on the merits." *Clark*, 74 F.4th at 640. The Court will therefore deny the Motion [7] and need not reach the other elements.

A. Plaintiff's Standing

Defendant takes the position that Plaintiff lacks standing to maintain this suit. *See* Memo [15] at 8–10. According to the Complaint [1], PhRMA is "a trade association representing the nation's leading innovative biopharmaceutical research companies." Compl. [1] at 9. Plaintiff claims its members "manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply their drugs at a steeply reduced price to Mississippi pharmacies under HB 728 or otherwise face significant criminal or civil penalties." *Id.* at 10. And it alleges that "[n]either the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA." *Id.*

Plaintiff has associational standing to bring this case. Associational standing derives from an association's members, and an association

> has standing to bring claims on behalf of its members when (1) individual members would have standing, (2) the association seeks to vindicate interests germane to its purpose, and (3) neither the claim asserted nor the relief requested requires the individual members' participation.

Students for Fair Admissions, Inc. v. University of Texas at Austin, 37 F.4th 1078, 1084 (5th Cir. 2022) (footnote omitted). In turn, individuals have standing to sue if they "(1) have suffered an injury in fact, (2) that is fairly traceable to the challenged action of the defendant, and (3) that will likely be redressed by a favorable decision." *Association of American Physicians & Surgeons Educational Foundation v. American Board of Internal Medicine*, 103 F.4th 383, 390 (5th Cir. 2024) (internal quotation marks and citation omitted).

The first two factors of the associational standing test "address constitutional requirements, while the third prong is solely prudential." *Ass'n of Am. Physicians & Surgeons, Inc. v. Texas Med. Bd.*, 627 F.3d 547, 550 (5th Cir. 2010) (citation omitted). "[N]either unusual circumstances, inability of individual members to assert rights nor an explicit statement of representation are requisites" to associational standing. *Church of Scientology of California v. Cazares*, 638 F.2d 1272, 1279 (5th Cir. 1981).

Here, the Court concludes that PhRMA's members have standing such that the first two factors, which "address constitutional requirements," *Ass'n of Am. Physicians & Surgeons*, 627 F.3d at 550, are met. Pharmaceutical manufacturers who claim federal law preempts Mississippi from, in effect, requiring them to ship 340B drugs to contract pharmacies face an "imminent threat of harm" in the form of prosecution. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007). This threat is not eliminated even "by simply not doing what [they] claim[] the right to do"; meaning manufacturers who accept being coerced into compliance with H.B. 728 still have a justiciable controversy with the State of Mississippi. *See id.* ("The dilemma posed by that coercion—putting the challenger to the choice between abandoning his rights or risking prosecution—is 'a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.'" (quoting *Abbott Laboratories v. Gardner,* 387 U.S. 136, 152 (1967)). Vindicating its members' interests in curbing alleged abuses of the Section 340B program, *see* Memo [8] at 8–

11, is also germane to Plaintiff's alleged purposes in promoting the development of new pharmaceutical products, *see* Compl. [1] at 9–10.

Turning to the third prong, the Court's analysis focuses on "matters of administrative convenience and efficiency." *United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 557 (1996). "Courts assess [the third] prong by examining both the relief requested and the claims asserted," *Ass'n of Am. Physicians & Surgeons*, 627 F.3d at 551, and "requests for declaratory or injunctive relief rarely require individual determinations," *Tex. Ass'n for Rights of Unemployed v. Serna*, 663 F. Supp. 3d 703, 711 (W.D. Tex. 2023) (internal quotation marks and citation omitted). On the other hand, "an association's action for damages running solely to its members would be barred for want of the association's standing to sue." *Brown Grp.,* 517 U.S. at 546. Insofar as evidence is needed, the Court should consider whether PhRMA's "claims can be proven by evidence from representative injured members, without a fact-intensive-individual inquiry." *Ass'n of Am. Physicians & Surgeons*, 627 F.3d at 552.

Defendant argues that Plaintiff lacks standing because one of its members, Novartis Pharmaceuticals Corporation ("Novartis"), has brought its own lawsuit. *See* Complaint, *Novartis Pharmaceuticals Corporation v. Fitch*, No. 1:24-cv-164 (S.D. Miss. June 3, 2024), ECF No. 1.[2] Defendant reasons that if Novartis saw fit to

[2] On June 27, 2024, the Court held a consolidated hearing on the present Motion [7] and Novartis's Motion for Preliminary Injunction, *Novartis Pharmaceuticals Corporation v. Fitch*, No. 1:24-cv-164 (S.D. Miss. June 4, 2024), ECF No. 4.

bring its own suit, then this case must require participation of individual members. The Court does not agree.

Both PhRMA and Novartis raise similar legal questions about H.B. 728 and the Section 340B program in which Novartis and PhRMA's other members participate. And both seek the same declaratory and injunctive relief. *Compare* Compl. [1] at 47, *with* Complaint, *Novartis Pharmaceuticals Corporation v. Fitch*, No. 1:24-cv-164 (S.D. Miss. June 3, 2024), ECF No. 1. Individual participation from PhRMA's members is not required in order for the Court to determine the constitutional validity of H.B. 728, or whether it should enjoin the Mississippi Attorney General from enforcing it. Nor is the Court persuaded that Novartis's actions in another case can pull the rug out from under PhRMA's standing. *See Daunt v. Benson*, 956 F.3d 396, 418 (6th Cir. 2020) (concluding an association had standing to sue when its individual members had filed their own claims). The Court therefore finds that PhRMA has associational standing to maintain this suit, and it will proceed to address the merits of Plaintiff's Motion [7].

B. Preemption generally

The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." Art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." *Arizona v. United States*, 567 U.S. 387, 399 (2012).

When a party raises preemption, "'[t]he purpose of Congress is the ultimate touchstone' of [the] analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)) (other citations and quotations omitted). Preemption may be "compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (internal quotation marks and citation omitted). But the Court cannot "assume[] lightly that Congress has derogated state regulation, but instead [should] address[] claims of pre-emption with the starting presumption that Congress does not intend to supplant state law." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). And "[d]eference to our federalism counsels a presumption that areas of law traditionally reserved to the states . . . are not to be disturbed absent the clear and manifest purpose of Congress." *In re Davis*, 170 F.3d 475, 481 (5th Cir. 1999) (en banc) (internal quotation marks and citations omitted).

Three categories of preemption exist: "when (1) a federal statute expressly preempts state law," ("express preemption"); "(2) federal legislation pervasively occupies a regulatory field," ("field preemption"); "or (3) a federal statute conflicts with state law," ("conflict preemption"). *Deanda v. Becerra*, 96 F.4th 750, 760–61 (5th Cir. 2024) (citing *Arizona*, 567 U.S. at 398–400). Plaintiff does not contend that Section 340B expressly preempts H.B. 728. *See generally* Memo [8]. Rather,

Plaintiff contends that the 340B Program implicitly preempts H.B. 728 under conflict preemption and field preemption. *Id.* at 15–30.

C. Section 340B does not preempt H.B. 728 under conflict preemption

Conflict preemption arises "where 'compliance with both state and federal law is impossible,' or where 'the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *California v. ARC America Corp.*, 490 U.S. 93, 100, 101 (1989)) (other internal quotation marks omitted). "In either situation, federal law must prevail." *Id.*

Plaintiff does not contend that compliance with both Mississippi and federal law is impossible. *See generally* Memo [8]. So, Plaintiff must show that Mississippi law "produce[s] a result inconsistent with the objective of the federal statute," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such that it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz,* 312 U.S. 52, 67 (1941). Plaintiff must meet "a high threshold" to succeed on such a theory. *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quoting *Chamber of Com. v. Whiting*, 563 U.S. 582, 607 (2011)), *cert. denied*, 144 S. Ct. 557 (2024). "Courts may not conduct 'a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle that it is

Congress rather than the courts that pre-empts state law.'" *Id.* (quoting *Whiting*, 563 U.S. at 607) (alteration in original).[3]

In a case like this one, "[p]reemption analysis begins 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Deanda*, 96 F.4th at 761 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). That is because a state law regulating health and safety falls within a state's traditional police powers. *See Hillsborough Cnty., Fla. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 710, 716 (1985) (holding that a local regulation of blood donation centers, including "donor testing and recordkeeping requirements beyond those contained in the federal regulations," was not preempted because the challenger did not "present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that [was] strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation"); *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 813 (5th Cir. 2011) (discussing how the Court should "begin with the assumption that Congress did not intend to supersede the historic police powers of the states to protect the health and safety of their citizens" (internal quotation marks and citation omitted)).

[3] In *Whiting*, the implied preemption analysis received only four votes, while Justice Thomas joined the rest of the opinion and concurred in the judgment, 563 U.S. at 586, likely because he had "become increasingly skeptical of [the Supreme] Court's 'purposes and objectives' pre-emption jurisprudence," *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring); *see Villas at Parkside Partners v. City of Farmers Branch, Tex.*, 675 F.3d 802, 829 n.5 (5th Cir. 2012) (Elrod, J., concurring in part and dissenting in part) (discussing Justice Thomas's fifth vote in *Whiting*), *on reh'g en banc*, 726 F.3d 524 (5th Cir. 2013).

House Bill 728 plainly falls under the umbrella of a health and safety regulation. It prohibits manufacturers from refusing to deliver Section 340B drugs to contract pharmacies, presumably to maximize covered-entity patients' access to drugs for which the manufacturers have already agreed to provide a discount. The state statute therefore triggers the presumption against preemption. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (plurality opinion of Stevens, J.) (applying "[t]he presumption against federal pre-emption of a state statute designed to foster public health" (citing *Hillsborough Cnty.*, 471 U.S. at 715–18), and rejecting a preemption claim challenging a Maine policy that subjected drug manufacturers' pharmaceuticals to prior authorization procedures before providing state Medicaid coverage for them unless the manufacturers agreed to provide rebates to Maine residents beyond rebates the Medicaid Act provides for); *Wyeth v. Levine*, 555 U.S. 555, 578 (2009) ("[T]he FDA traditionally regarded state law as a complementary form of drug regulation."); *McClain*, 95 F.4th at 1144 (holding that Section 340B does not preempt state law prohibiting manufacturers from precluding covered entities from making dispensation contracts with pharmacies in part because "[p]harmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted").

True, in *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372 (5th Cir. 2012), the Fifth Circuit expressed uncertainty about the strength and scope of

the presumption against preemption. 672 F.3d at 378–79. But *Lofton* merely observes that "whatever value or relevance a presumption against preemption of state tort law should play is uncertain" given its observation that the Supreme Court's "majority opinion in [*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)] made no reference to the 'presumption' in the course of upholding implied conflict preemption over state law claims for failure to maintain adequate warning labels for FDA-approved generic drugs." 672 F.3d at 378. *Lofton*'s statements about the scope of the presumption against preemption do not mean that the presumption against preemption no longer applies.

Further, *Lofton*'s statement that "the primacy of the state's police powers is not universal" is inapplicable here. *Id.* *Lofton* discussed state-law tort claims based on fraud on the FDA. *See id.* at 378–79. In that context, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 378 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001)). House Bill 728 does not purport to prohibit fraud on a federal agency.

Nor does *Teltech Sys., Inc. v. Bryant*, 702 F.3d 232 (5th Cir. 2012), relied upon by PhRMA, indicate that the presumption against preemption should not apply here. *Teltech*, in addressing a Mississippi statute that prohibited the use of a fake caller ID to deceive the recipient of a phone call, explained that "[a]lthough interstate telecommunications has been an area of significant federal presence, [the

Mississippi law] is grounded instead in consumer protection, an area traditionally reserved to the States. Therefore, here the presumption remains in favor of no preemption." 702 F.3d at 236 (internal quotation marks and citations omitted). Though *Teltech* concluded the Mississippi statute was preempted, it applied the presumption against preemption based on the state's police power to protect consumers, notwithstanding that federal law had traditionally regulated interstate telecommunications. *See id.* Here, the Court finds that H.B 728 aims to promote the health and welfare of its citizens and triggers the presumption against preemption, even if it applies to "an area of significant federal presence." *Id.* (internal quotation marks and citations omitted).

Applying the presumption against preemption, the Court does not find that Section 340B exhibits a clear purpose to preempt state laws that would require manufacturers to deliver covered entities' drugs to contract pharmacies for distribution. Section 340B does not explicitly mandate how delivery of discounted drugs is to occur. *See McClain*, 95 F.4th at 1142 ("[T]he 340B Program 'is silent about delivery' and distribution of pharmaceuticals to patients." (quoting *Sanofi Aventis*, 58 F.4th at 703)).[4] Section 340B merely requires participating manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." § 256b(a)(1).

[4] Section 340B discusses distribution, directing the Secretary to "establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs," and providing, "*If* a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution." § 256b(a)(8) (emphasis added). Section 256b(a)(8) do not mandate how delivery is to occur.

Sanofi Aventis and *Novartis* concluded that, under the terms of Section 340B, HHS may not *require* manufacturers to ship drugs intended for covered-entity patients to any contract pharmacy the entity deals with. *Sanofi Aventis*, 58 F.4th at 703 (concluding that "Section 340B does not require delivery to an unlimited number of contract pharmacies"); *Novartis*, 102 F.4th at 460–63. But the same "statutory silence[]," *Sanofi Aventis*, 58 F.4th 699, that does not *implicitly mandate* that manufacturers deliver to any contract pharmacy does not, on the other hand, show that Congress clearly intended to *preclude states* from enacting their own public health regulations aimed at maximizing the availability of low-cost drugs for covered-entity patients, *see McClain*, 95 F.4th at 1145 (concluding that "the delivery of a covered entity's 340B drugs to contract pharmacies for dispensing creates no obstacle" to Section 340B's objectives). If anything, H.B. 728 arguably promotes Section 340B's objective of ensuring covered-entity patients can conveniently access their medications. *See id.* at 1144–45 (explaining how Arkansas's prohibition on manufacturers preventing covered entities from contracting with pharmacies for drug distribution "does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [the law] assists in fulfilling the purpose of 340B").

The upshot of Plaintiff's argument is that Congress deliberately left to pharmaceutical manufacturers the discretion to refuse to ship 340B discounted drugs to contract pharmacies simply because it was silent in the statute about delivery. *See* Memo [8] at 24 (citing *Novartis*, 102 F.4th at 460). Plaintiff is correct

that federal law can preempt state law when Congress, or a federal agency implementing federal law, makes a policy choice that balances competing objectives in such a way that a state regulation aimed at the same subject matter upsets the balance that the federal government struck. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 864–81 (2000). But that is not this case.

In *Geier*, for example, the Court held that a Department of Transportation regulation, FMVSS 208, requiring automobile manufacturers to equip some, but not all, of their 1987 vehicles with passive restraints—such as airbags—preempted state tort law requiring airbags beyond what that regulation required. *Id.* at 864–65. But there, the Supreme Court found that "clear evidence of a conflict" existed between state tort law and the regulation. *Id.* at 885. The Court reached this conclusion based on the agency's "contemporaneous explanation" of several "significant considerations" it had in mind in designing the regulation. *See id.* at 877–81. The regulation "deliberately provided [car manufacturers] with a range of choices among different passive restraint devices," so as to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 875.

Here, Plaintiff does not persuasively show, at least at this stage of the proceedings, how H.B. 728 creates a substantial obstacle to Section 340B's purposes, or what consideration Congress had in mind in not addressing delivery of 340B drugs. In other words, there is no clear evidence of an "actual," "significant" conflict. *Id.* at 884–85 (internal quotation marks and citation omitted). House Bill

728 does not require pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expand the definition of what a 340B healthcare provider is, or expand the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs. House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for distribution—something Section 340B may not require, but does not implicitly preclude either.

To the extent that delivering discounted drugs to contract pharmacies raises the risk of diversion, Section 340B prohibits diversion and provides for comprehensive enforcement mechanisms. *See supra*, Part I.A. If Section 340B healthcare providers are conspiring with pharmacies to divert discounted drugs, HHS can require the provider to compensate the manufacturer for its losses, § 256b(a)(5), and remove the provider from the program, § 256b(d)(2)(B)(v)(II). The Court is not prepared to find Section 340B likely preempts H.B. 728 on a theory that Congress's remedial scheme under Section 340B is inadequate to deter violations of federal law. As written, H.B. 728 and Section 340B do not conflict.

Congress also increased enforcement mechanisms against diversion in the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 7102, 124 Stat. 119 (enacted March 23, 2010), by adding § 256b(d), *id.* at 823–26, 18 days after the 2010 HRSA Guidance that advised that covered entities can use an unlimited number of contract pharmacies, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). Thus,

Congress was presumably aware of the potential for diversion through the use of an unlimited number of contract pharmacies, and it increased enforcement against diversion, yet remained silent about delivery—not to mention about preemption. And while "failures to enact legislation 'are not reliable indicators of congressional intent,'" *Novartis*, 102 F.4th at 462 (quoting *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989)), Plaintiff's argument relies on an inference of preemptive intent from Congress's silence as to delivery, so the Court considers legislative context relevant in interpreting that silence, *see Arizona*, 567 U.S. at 405–406 (discussing policy proposals Congress did not enact in analyzing preemption).[5]

Plaintiff also argues that "H.B. 728's limitations on data access and the collection of claims data . . . will prevent manufacturers from utilizing the federal ADR process and determining if duplicate discounting is occurring." Memo [8] at 26. The Court is not persuaded that H.B. 728 actually limits data access for manufacturers.

Plaintiff asserts that "H.B. 728 broadly prohibits manufacturers from 'interfer[ing]' with 'the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity'" or from "'interfer[ing] with a pharmacy contracted with a 340B entity.'" *Id.* (quoting H.B. 728, § 4). While the term "interfere" is fairly broad, the Court is not persuaded that it prohibits any data

[5] Ordinarily, it is the party claiming preemption that will "rely on legislative history to demonstrate Congress" intended to preempt state law by inaction. *TelTech*, 702 F.3d at 238. For that reason, Justice Thomas has noted his skepticism of purposes and objectives preemption, arguing that, under it, "the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law." *Wyeth*, 555 U.S. at 583 (Thomas, J., concurring in the judgment).

collection efforts by a manufacturer. The obvious point of H.B. 728, as explained in Plaintiff's discussion of the Section 340B program, *see* Memo [8] at 6–13, is to prevent manufacturers from refusing to deliver 340B drugs purchased by covered entities to contract pharmacies. Importantly, H.B. 728 states that it should not be construed to conflict with federal law, H.B. 728 § 6, and the Court must apply the presumption against preemption to construe state laws not to conflict with federal law when possible, *see Fox v. Washington*, 236 U.S. 273, 277 (1915) ("So far as statutes fairly may be construed in such a way as to avoid doubtful constitutional questions they should be so construed; and it is to be presumed that state laws will be construed in that way by the state courts." (citation omitted)). And "conflict preemption is not triggered by ordinary incongruities or minor annoyances" that upset any federal-state balance "to some extent." *Barrosse*, 70 F.4th at 323. Accordingly, the Court does not find that any potential data-collection issue between manufacturers and covered entities is sufficiently clear or substantial to show H.B. 728 is preempted.

In arguing that H.B. 728 conflicts with data-collection efforts, Plaintiff also cites H.B. 728 § 3(1)(a)(ii)(5), which prohibits a health insurance company or third-party payor from imposing

> [r]equirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted *unless it is required by the Centers for Medicare and Medicaid Services or the Division of Medicaid for the administration of the Mississippi Medicaid program*.

H.B. 728 § 3(1)(a)(ii)(5) (emphasis added). Plaintiff contends that, in recent guidance on how to comply with 42 U.S.C. § 1320f-3, under which HHS is to

"negotiate" with manufacturers the "maximum fair price[s]" for certain drugs, § 1320f(3)(a), "the Centers for Medicare and Medicaid Services," ("CMS") "has encouraged dispensing entities to use claims codes indicating when drugs are dispensed under the 340B program." Memo [8] at 27 (citing Draft Guidance on the Medicare Drug Price Negotiation Program, https://www.cms.gov/files/document/medicare-drug-price-negoti ation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf (last visited June 28, 2024)). According to Plaintiff, "[t]o avoid duplicate discounting, this scheme necessarily requires identifying when a drug is dispensed as a 340B drug." *Id.* Even assuming Plaintiff has standing to claim a regulation of healthcare insurers or other third-party payors is preempted, H.B. 728, § 3(1)(a)(ii)(5) likely protects itself from preemption through its exception for cases when CMS requires identifications or other modifiers indicating a drug is a 340B drug.

In addition, Plaintiff argues that H.B. 728 conflicts with Section 340B's enforcement mechanisms because Congress intended that only the federal government oversee Section 340B. Memo [8] at 27–28 (citing *Astra*, 563 U.S. at 113). The Court disagrees: H.B. 728 addresses delivery and Section 340B does not, so adjudications under H.B. 728 will not interfere with federal enforcement of Section 340B's compliance mechanisms. *Astra* held that covered entities lack a cause of action as third-party beneficiaries to PPA's to sue manufacturers for overcharging them for 340B drugs. 563 U.S. at 118–19. An overcharging claim[6] is

[6] Section 340B provides for administrative enforcement against overcharging by manufacturers in § 256b(d)(1).

different from a claim that the manufacturer interfered with a covered entity's contract with a pharmacy. *See McClain*, 95 F.4th at 1144 (concluding an Arkansas law similar to H.B. 728 "ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies," while "[t]he 340B Program . . . addresses discount pricing").

The Court therefore concludes that Plaintiff has not shown a substantial likelihood that it will succeed on the merits of its conflict-preemption claim.

D. Section 340B does not preempt H.B. 728 under field preemption

The Court is also unpersuaded that Section 340B preempts H.B. 728 under a theory of field preemption. Field preemption requires that Congress has passed such comprehensive legislation in an area that it has "occupied the field." *Arizona*, 567 U.S. at 401. Congress's intent to displace state law can be inferred from its enactment of a federal regulatory scheme "'so pervasive . . . that Congress left no room for the States to supplement it' or where there is a 'federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* at 399 (quoting *Rice*, 331 U.S. at 230). Field preemption "should not be inferred, however, simply because the agency's regulations are comprehensive." *R.J. Reynolds Tobacco Co. v. Durham Cnty., N.C.*, 479 U.S. 130, 149 (1986).

"Field preemption of state law is disfavored." *Nat'l Press Photographers Ass'n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). The Fifth Circuit has emphasized that "Courts should not infer field preemption in 'areas that have been traditionally occupied by the states,' in which case congressional intent to preempt must be 'clear and manifest.'" *Id.* (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). "And importantly, field preemption is not to be found where federal 'regulations, while detailed, appear to contemplate some concurrent state regulation.'" *Id.* (quoting *R.J. Reynolds Tobacco*, 479 U.S. at 149).

House Bill 728 implicates a traditional area of state regulation, triggering the presumption against preemption, *see supra*, Part II.C., and rendering inapplicable *Arizona*'s discussion of dominant federal interests, *see Arizona*, 567 U.S. at 399. Section 340B also does not control how manufacturers must deliver discounted drugs to patients of covered entities. *See supra*, Part II.C. Section 340B thus leaves room for states to impose their own regulations on delivery of Section 340B drugs to promote patients' access to their medications. "[M]erely because [Section 340B is] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field." *Hillsborough Cnty.*, 471 U.S. at 717. While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs and provides robust enforcement mechanisms that ensure covered entities and manufacturers comply with the statute's requirements, *see supra*, Part

I.A., Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs.

The Court is also not persuaded that field preemption is compelled by *Astra*'s holding that covered entities cannot bring overcharging claims as third-party beneficiaries to PPAs. *See Astra*, 563 U.S. at 117–19. *Astra* rejected an argument that, despite a covered entity's "inability to assert a statutory right of action" under Section 340B itself, "PPAs implementing the 340B Program are agreements enforceable by covered entities as third-party beneficiaries." *Astra*, 563 U.S. at 117. Because PPAs are essentially contracts whereby manufacturers opt into Section 340B, the Court reasoned that "[a] third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself." *Id.* at 118. Accordingly, "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.*

The Supreme Court's rejection of a right of action for covered entities under PPAs has minimal bearing on whether Section 340B preempts state law about the delivery of 340B drugs. And *Astra* did not apply any presumption in favor of such a right of action analogous to the presumption against preemption applicable here. *See Arizona*, 567 U.S. at 400 ("In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." (internal quotation marks and citations

omitted)). The Court therefore concludes that Plaintiff has not shown a substantial likelihood of success on the merits of its field preemption claim.

E. Plaintiff has not shown a substantial likelihood of success on the merits of its Constitutional claims based on extraterritoriality

Plaintiff also argues that H.B. 728 violates the Constitution because it constitutes an extraterritorial regulation. Plaintiff raises this claim under the Commerce Clause, U.S. Const. art. I, § 8, cl. 3, and the Fourteenth Amendment's Due Process Clause, U.S. Const. amend. XIV, § 1. The Court is unpersuaded.

Plaintiff first invokes the principle that the "Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.,* 457 U.S. 624, 642–43 (1982) (plurality opinion)); *see* Memo [8] at 30–31. It is first worth noting that the Supreme Court recently discussed how *Healy* does not establish any "*per se* rule against state laws with extraterritorial effects." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 373 (2023) (internal quotation marks omitted). Rather, *Healy* concluded that a Connecticut law had a "*specific* impermissible 'extraterritorial effect'—[it] deliberately 'prevent[ed out-of-state firms] from undertaking competitive pricing' or 'deprive[d] businesses and consumers in other States of "whatever competitive advantages they may possess."'" *Id.* at 374 (quoting *Healy*, 491 U.S. at 338–39 (quoting *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 580 (1986))) (first alteration added). *National Pork Producers* also clarifies that the "antidiscrimination principle lies at the very

core of our dormant Commerce Clause jurisprudence," meaning "the Commerce Clause prohibits the enforcement of state laws driven by . . . economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 369 (internal quotation marks and citations omitted).

Here, Plaintiff does not argue that H.B. 728 discriminates against out-of-state commerce. *See* Memo [8] at 30–32. It instead contends that H.B. 728 violates the Commerce Clause because it "*directly* regulate[s] out-of-state transactions by those with *no* connection to the State," a Constitutional claim that *National Pork Producers* noted may not be a "Commerce Clause question as much as one testing the territorial limits of state authority under the Constitution's horizontal separation of powers." 598 U.S. at 376 n.1; Memo [8] at 31. Plaintiff also cites "the due process principle that a state is without power to exercise extra territorial jurisdiction, that is, to regulate and control activities wholly beyond its boundaries." *Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954) (internal quotation marks omitted); *see* Memo [8] at 31–32. However the claim is framed, the United States Constitution does not permit Mississippi to directly regulate out-of-state conduct without a connection to the state. But House Bill 728 does not do so.

Under Mississippi law, "[u]nless the intention to have a statute operate beyond the limits of the state or country is clearly expressed or indicated by its language, purpose, subject matter, or history, no legislation is presumed to be intended to operate outside the territorial jurisdiction of the state or country

enacting it." *Tattis v. Karthans*, 215 So. 2d 685, 689 (Miss. 1968). Rather, a Court interpreting Mississippi law applies a "presumption [] that [a] statute is intended to have no extraterritorial effect." *Id.* This Court should therefore construe the statute to "apply only within the territorial jurisdiction of the state or country enacting it." *Id.* "Accordingly, a statute is prima facie operative only as to persons or things within the territorial jurisdiction of the lawmaking power which enacted it," and this presumption "appl[ies] to statutes using general words, such as 'any' or 'all,' in describing the persons or acts to which the statute applies." *Id.* at 689–90. The presumption against extraterritoriality is "particularly applicable where the statute would be declared invalid if given an interpretation resulting in its extraterritorial operation." *Id.* at 690. If not for this presumption, every state law in every state would potentially need a disclaimer that it only applies to in-state conduct, which bread-and-butter state laws often lack. *See, e.g.*, Miss. Code Ann. § 97-3-19 (defining "murder" and "capital murder" without explicitly limiting the crime to conduct taking place in Mississippi).

House Bill 728 does not exhibit a clear intent to regulate out-of-state conduct. It provides that pharmaceutical manufacturers[7] "shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a

[7] House Bill 728 § 2(d) defines "manufacturer" by referencing Miss Code. Ann. § 73-21-73, which provides: "'Manufacturer' means a person, business or other entity engaged in the production, preparation, propagation, conversion or processing of a prescription drug or device, if such actions are associated with promotion and marketing of such drugs or devices." Miss Code. Ann. § 73-21-73(t).

340B entity," or "interfere with a pharmacy contracted with a 340B entity." H.B. 728 § 4. The House Bill's "general words" referring to 340B entities, manufacturers, and pharmacies are "prima facie operative only as to persons or things within the territorial jurisdiction of" Mississippi. *Tattis*, 215 So. 2d at 689–90. To the extent that the definitions of any of those terms might, in the abstract or by reference to other provisions of Mississippi law, literally include out-of-state entities, the Court finds that H.B. 728 must be construed to only regulate conduct occurring "within the territorial jurisdiction of the state." *Id.* The Court thus concludes that Plaintiff has not shown it is likely to succeed on the merits of its extraterritoriality claim.

F. Plaintiff not shown a substantial likelihood of success on the merits of its vagueness claim

The Court finally turns to Plaintiff's claim that H.B. 728 is unconstitutionally vague. The Due Process Clause "proscribes laws so vague that persons of common intelligence must necessarily guess at [their] meaning and differ as to [their] application." *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001) (internal quotation marks and citation omitted). "A law that does not reach constitutionally protected conduct" is not "unduly vague, in violation of due process," unless "the complainant [can] demonstrate that the law is impermissibly vague in all of its applications." *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 497 (1982). "The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Id.* at 498. "[E]conomic regulation is subject to a less strict vagueness test because its subject matter is often more

narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action." *Id.* (citation omitted). The Supreme Court "has also expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are qualitatively less severe," though "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." *Id.* at 498–99.

But "[w]hen speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech." *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253–54 (2012). Plaintiff argues that H.B. 728 regulates speech in an unconstitutionally vague manner. According to Plaintiff:

> The Act's vague and broad prohibition on interference would appear to bar manufacturers from a host of actions, including precluding a wide swath of speech. Specifically, as to 340B, the Act seems to block manufacturers from requesting information from covered entities and contract pharmacies that is necessary to utilize the federal 340B audit and ADR mechanism, and potentially keeps manufacturers from reporting misconduct to the federal government. Similar considerations demonstrate the Act's impact on speech. Manufacturers are prohibited from engaging in "interference" with a pharmacy. That vague language would seem to prohibit manufacturers from even advocating for the position that 340B limits the use of contract pharmacies or making statements regarding contract pharmacy usage that are perceived as unfavorable.

Memo [8] at 33. Plaintiff focuses its argument on the term "interfere," arguing that "[l]aws that prohibit 'interference' are notoriously vague." *Id.* (citing *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023)).

The Court first addresses Plaintiff's contention that H.B. 728 infringes on its First Amendment rights. Plaintiff cites no authority to support its position that

requesting information from covered entities is protected speech under the First Amendment. *See id.* at 32–33. House Bill 728 also does not actually prohibit manufacturers from requesting information from covered entities. *See supra*, Part II.C. Because the Court must construe state laws not to conflict with federal law when possible, *see Fox*, 236 U.S. at 277, the Court likewise does not find that H.B. 728 prohibits manufacturers from exercising their audit rights under § 256b(a)(5)(C) or otherwise reporting misconduct to HRSA or HHS. And the Court is entirely unconvinced that H.B. 728 purports to prohibit manufacturers from engaging in any policy advocacy.

Accordingly, H.B. 728 is an "economic regulation [that] is subject to a less strict vagueness test" than that applicable to a law that infringes on constitutional rights. *Vill. of Hoffman Ests.*, 455 U.S. at 498. Under this less strict standard, the term "interfere" does not render H.B. 728 unconstitutionally vague.

"[P]ersons of common intelligence" would not "necessarily guess at" H.B. 728's meaning. *Women's Med. Ctr. of Nw. Houston*, 248 F.3d at 421 (internal quotation marks and citation omitted). Black's Law Dictionary defines "interference" as "[t]he act or process of obstructing normal operations or intervening or meddling in the affairs of others." Interference, *Black's Law Dictionary* (11th ed. 2019). House Bill 728 thus prohibits manufacturers from "obstructing [the] normal operations" of, "or intervening or meddling in the affairs" of a contract pharmacy receiving and dispensing 340B drugs to 340B patients.

The statute plainly requires manufacturers to deliver 340B drugs to contract pharmacies and prohibits manufacturers from obstructing contract pharmacies in their dispensation of 340B drugs. The Court need not determine the precise contours of the statute in every hypothetical application because Plaintiff's "facial challenge may only be sustained if the enactment is impermissibly vague in all of its applications." *McClelland v. Katy Indep. Sch. Dist.*, 63 F.4th 996, 1013 (5th Cir. 2023) (internal quotation marks and citation omitted), *cert. denied*, 144 S. Ct. 348 (2023), *reh'g denied*, 144 S. Ct. 629 (2024).

House Bill 728's context and history also clarify its meaning. The word "interfere" in H.B. 728 "should be 'interpreted in its statutory and historical context and with appreciation for its importance to the [statute] as a whole.'" *Texas v. Biden*, 646 F. Supp. 3d 753, 767 (N.D. Tex. 2022) (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 471 (2001)), *appeal dismissed*, No. 23-10143, 2023 WL 5198783 (5th Cir. May 25, 2023). The history behind H.B. 728, recounted *supra* in Parts I.A.–B., indicates that H.B. 728 requires manufacturers who have agreed to offer discounted drugs to covered entities under Section 340B to deliver those drugs to contract pharmacies for dispensation without otherwise interfering with covered entities' agreements with contract pharmacies.

The other terms H.B. 728 employs also inform its meaning. House Bill 728 provides that "[a] manufacturer or distributor shall not deny, restrict, [or] prohibit . . . the acquisition of a 340B drug by, or delivery of a 340B drug to, a" contract pharmacy. H.B. 728 § 4(a). Section (4)(a) plainly mandates that manufacturers

deliver 340B drugs to contract pharmacies. To the extent that the concept of interference is unclear, § 4 confirms that H.B. 728 was written to ensure manufacturers deliver 340B drugs to contract pharmacies.

True, criminal laws must be clearer than laws carrying only civil liability. *Vill. of Hoffman Ests.*, 455 U.S. at 498–99. House Bill 728 creates criminal liability, but only for violations committed "knowingly and willfully." Miss Code Ann. § 75-24-20(a). This high mens rea requirement mitigates any vagueness there may be. *See Vill. of Hoffman Ests.*, 455 U.S. at 498–99.

"The word 'willful' is sometimes said to be a word of many meanings whose construction is often dependent on the context in which it appears." *Bryan v. United States*, 524 U.S. 184, 191 (1998) (internal quotation marks and citation omitted). But generally speaking, "willfully" means "undertaken with a 'bad purpose,'" such that, "in order to establish a 'willful' violation of a statute, 'the Government must prove that the defendant acted with knowledge that his conduct was unlawful.'" *Id.* at 191–92 (quoting *Ratzlaf v. United States*, 510 U.S. 135, 137 (1994)) (other citations omitted); *see also Fortune v. State*, 110 So. 3d 831, 835 (Miss. Ct. App. 2013) (quoting trial court jury instructions defining "willfully" to "mean[] that the act was committed voluntarily and purposely, with the specific intent to do something the law forbids; that is to say, with [a] bad purpose either to disobey or disregard the law"). Because Miss. Code. Ann. § 75-24-20 also uses the term "knowingly," avoiding superfluity demands reading "willfully" in the elevated sense discussed above. *See Hoops v. State*, 681 So. 2d 521, 534 (Miss. 1996) (explaining

how, as used in jury instructions, "[t]he phrase 'knowingly and wilfully' contemplates that the accused must act with knowledge and deliberation; therefore, the instruction does not deem mere knowledge sufficient to find one guilty"), *abrogated on other grounds by Nash v. State*, 293 So. 3d 265 (Miss. 2020), and *Willis v. State*, 300 So. 3d 999 (Miss. 2020). Accordingly, the high mens rea requirement under Miss. Code. Ann. § 75-24-20 avoids any constitutional vagueness issue based on criminal liability that might result from enforcement of H.B. 728.

It is also worth noting that Miss. Code Ann. § 75-24-19 imposes the same high, "knowing[] and willfull[]" scienter requirement in a civil action by the state Attorney General seeking damages. *See* Miss. Code Ann. § 75-24-19(1)(b). So, if the manufacturer does not commit a knowing and willful violation of H.B. 728, the only available relief is an injunction under Miss. Code Ann. § 75-24-9. Such *prospective* relief would require a court order that must "describe in reasonable detail . . . the act or acts sought to be restrained," Miss R. Civ. P. 65(d)(1), providing additional notice to a manufacturer found to have violated H.B. 728 before a court could impose monetary damages. All told, the Court does not find that Plaintiff has shown a substantial likelihood of success on the merits of its vagueness claim.

III. CONCLUSION

Because Plaintiff has not shown a substantial likelihood of success on the merits as required to obtain a preliminary injunction, it is not entitled to such relief, and the Court need not address the remaining Rule 65 factors. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 23–24 (2008) (declining to address other

preliminary injunction factors after finding against the plaintiffs on one such factor). To the extent the Court has not addressed any of the parties' remaining arguments, it has considered them and determined they would not alter the Court's conclusion.

IT IS, THEREFORE, ORDERED AND ADJUDGED THAT, Plaintiff Pharmaceutical Research and Manufacturers of America's Motion [7] for Preliminary Injunction is **DENIED**.

SO ORDERED AND ADJUDGED, this the 1st day of July, 2024.

s/ Halil Suleyman Ozerden
HALIL SULEYMAN OZERDEN
UNITED STATES DISTRICT JUDGE